

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and EMORY
UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**REPLY MEMORANDUM IN SUPPORT OF GILEAD'S MOTION TO
DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS
ARGUMENT**

Mylan does not dispute:

- 1) that it never revealed the substance of its indefiniteness argument to Gilead prior to Mylan's responsive claim construction brief, either during the meet and confer discussions between the parties or in any discovery response;¹
- 2) that Gilead could not have responded to Mylan's indefiniteness argument before it was made; or
- 3) that the scheduling order in this case bars dispositive motions until after the close of discovery.

Mylan instead argues that “[t]he indefiniteness issue regarding the 24-hour claims is ripe for resolution during Markman, because the claim terms at the heart of the argument are being construed.” Response to Gilead's Motion to Defer Consideration of Mylan's Indefiniteness Argument or, Alternatively, for Leave to File a Reply (“Response”) at 2. Mylan is wrong on both the facts and the law.

In fact, the claim construction dispute focuses on the meaning of the word “a” in the term “less than [x%] degradation over *a* 24 hour period.” (Emphasis added.) Both parties and their experts have asserted that one skilled in the art would understand that word, and the entire claim term in dispute. The parties merely disagree about what that understanding would be. But “[a] claim is not indefinite merely because parties disagree concerning its construction.” *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010).

In this case, the “heart of the dispute” between the parties is which of those competing claim constructions is correct. Contrary to its assertion, Mylan's indefiniteness argument does not go to the heart of that dispute because Mylan argues that the entire claim term is indefinite *regardless* of whether the Court adopts its or Gilead's proposed claim construction.

¹ Indeed, Mylan only added its indefiniteness argument to its discovery responses the day *after* filing its Response to Gilead's Motion to Defer Consideration of Mylan's Indefiniteness Argument.

Dey, L.P. v. Teva Parenteral Medicines, Inc., 2011 WL 2461888 (N.D.W.Va. June 17, 2011), cited by Mylan, is not to the contrary. In that case, unlike here, Teva did not argue that the claim term was indefinite under any construction. Rather, Teva argued that the Court should reject Dey's construction and adopt Teva's, because Dey's construction (alone) rendered the claims indefinite. *Id.* at **3,6 Thus, in *Dey*, Teva's argument **did** go to the heart of the dispute—which of the competing constructions was correct. Mylan makes no such argument here—it offers its own construction and then argues indefiniteness under any construction.

Mylan's other cited cases are no more relevant. In *Interval Licensing LLC v. AOL, Inc.*, the claim terms “in an unobtrusive manner” and “does not distract a user” were deemed insolubly ambiguous and incapable of construction. *See Interval Licensing, LLC v. AOL, Inc.*, 2013 WL 792791, at **3-5 (W.D. Wa. Feb. 28, 2013), *aff'd in part and vacated in part*, 766 F.3d 1364 (Fed. Cir. 2014). That is not so here, where both parties and their experts have opined that one skilled in the art would understand the term “less than [X%] degradation over a 24 hour period.” The parties simply disagree over which understanding is correct. The *dicta* in *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999), that “[w]e have previously observed that an analysis under § 112, ¶ 2 is inextricably intertwined with claim construction,” is not a command that all indefiniteness arguments must be considered during claim construction. *Personalized Media Communications, LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998), cited in *Atmel* as the source for that observation simply says: “A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims.” Indeed, the Federal Circuit has never held that the indefiniteness analysis **must** be conducted during claim construction. And, as cited in Gilead's Motion, other district courts have, in fact, concluded that the “weight” of authority disfavors

determining indefiniteness at the Markman stage. *See* Gilead's Motion to Defer Consideration of Mylan's Indefiniteness Argument or, Alternatively, for Leave to File a Reply at 3-4.

Mylan is also incorrect that discovery is irrelevant to indefiniteness. At a minimum, Gilead is entitled to test the assertions of Mylan's expert in deposition after full disclosure of all of his opinions and to have its own expert provide opinion evidence to the Court. Fact and expert discovery are also likely to provide evidence regarding how one skilled in the art would understand the 24-hour limitation in view of the intrinsic evidence. Moreover, Mylan has offered only hypothetical examples in support of its argument—discovery is likely to show Mylan's hypotheticals are irrelevant or incredible. For example, Mylan apparently had no difficulty in understanding the claim language when it decided to challenge the patents-in-suit—it alleged neither indefiniteness nor non-infringement of the claims at issue in its notice letters to Gilead.² *See, e.g., Procter & Gamble Co. v. Team Technologies, Inc.*, 2014 WL 4626011, at **4-5 (S.D. Ohio Sept. 15, 2014) (noting that ability of defendants' lawyers to understand the claims in preparing opinion letter and conducting prior art search was "strong evidence" against indefiniteness).

Accordingly, the Court should grant Gilead's Motion to Defer Consideration of Mylan's Indefiniteness Argument. Should the Court decide to consider the issue of indefiniteness at this preliminary stage, Gilead's alternative request for leave to file a reply brief is unopposed by Mylan, and leave should be granted.

Finally, leaving aside Mylan's rhetoric, its Response confirms that there is a ripe dispute regarding whether the term "fixed-dose combination" is a limitation on the claims. Accordingly, Gilead intends to argue at the Markman hearing, as it did in footnote 5 of its Opening Brief in

² Indeed, Mylan understood the term sufficiently to assert in its Paragraph IV notice letters and interrogatory responses that the asserted claims are invalid as "obvious."

Support of Its Proposed Claim Constructions for U.S. Patent Nos. 8,592,397 and 8,716,264, that this term is a limitation on the claims, with the meaning already agreed to by the parties.

Dated: March 30, 2015

Respectfully submitted,

/s/Chad L. Taylor

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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2015, the foregoing **REPLY MEMORANDUM IN SUPPORT OF GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS ARGUMENT** was served upon the attorneys of record for Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. using the CM/ECF system, which will send notification of the filing to the counsel of record for Mylan Inc. and Mylan Pharmaceuticals Inc.

/s/Chad L. Taylor

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